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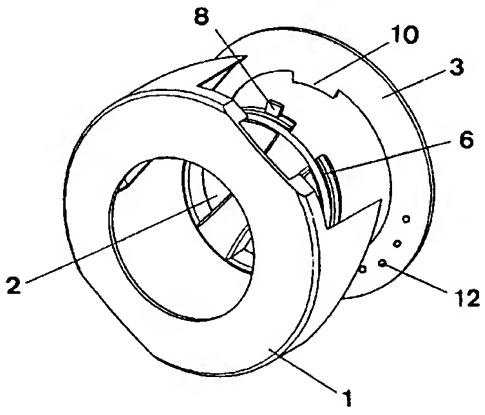
(54) Title: A DOSE SETTING LIMITER



(57) Abstract: A dose setting limiter for a medical injector. The dose setting limiter comprises of three parts. A first part formed as a shell with a plurality of flanges, which flanges fits retentively over the housing of the medical injector, a second part formed as a dose setting dial and fitted over the rotary dose setting knob of the medical injector and a third part placed between the first part and the second part. The second part is rotational connected to first part while the third part is locked to the first part when the first part is connected to the housing of the medical injector. The maximal allowable dose is preselected with the dose setting limiter disconnected from the housing of the medical injector by rotating the third part until the marker on the third part is placed over the desired maximal allowable dose indication on the scale located on the first part. Afterwards the first part is connected to the housing of the medical injector thereby locking the third part to the first part. When dialling the pointer on the second part clockwise a protrusion provided on the second part will abut another protrusion located on the third part once the preselected desired dose is reached, thereby preventing larger doses from being set.

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A dose setting limiter

The Technical field of the invention:

The invention relates to a dose setting limiter for medical injectors of the type having a housing accommodating an ampoule containing medicine sufficient for a number of dosed injections, a rotary dose setting knob, which is rotational relative to the housing and by which doses may be set by rotating the dose setting knob and an injection button which, when pressed, administers the set dose.

Description of related art:

Commercially accessible medical injectors of the above mentioned type are normally capable of being set to dispense a wide range of doses. Some medication, such as insulin, is often self-administered. The typical diabetes patients will require injections of insulin several times during the course of the day. Normally the size of the doses is prescribed and the dose setting knob of the injection device is therefore always rotated to the same amount before each injection. Due to this there is a great need for an auxiliary dose setting limiter, which can be applied to a medical injector, and which can help setting up the exact same dose every time.

An auxiliary dose setting limiter of this kind is known from WO 99.64092. This dose setting limiter is cup-shaped and is placed retentively over the dose setting knob in a position where a projection on the dose setting limiter aligns the desired dose. When in use, the injection dose is first being set by rotating the dose setting knob, which knob can only be rotated until the pre-set dose is reached, while the projection on the dose setting limiter will be arrested by a stationary raised stud on the injection pen. This known dose setting limiter can only be applied to a traditional pencil-shaped injection device of the type having the dose setting knob placed at the rear end of the pen and a stationary raised stud indicating the zero mark of the scale.

Disclosure of the invention:

It is an object of the invention to provide a dose setting limiter, which can be fitted on to a large variety of injection devices. It is a particular object to provide a dose setting limiter that can be fitted on to the new generation of very short injection devices e.g. known from US 5.947.934.

This is obtained by a dose setting limiter for medical injectors of the type having a housing accommodating an ampoule containing medicine sufficient for a number of dosed injections, a rotary dose setting knob, which is rotational relative to said housing and by which doses may be set by rotating said dose setting knob and an injection button which, when activated, administers the set dose, said dose setting limiter comprising:

a stationary first part connected to said housing, and

a second part fitted over said rotary dose setting knob, said second part being able to rotate together with said dose setting knob when setting up a dose and said second part being rotational relatively to said first part,

which dose setting limiter according to the invention is characterised in that a third part is placed between said first part and said second part, said third part having means co-operating with means on said second part for limiting the dose setting.

The desired dose is first being set by rotating the third part with the auxiliary dose setting limiter disconnected from the injection device. When the marker on the third part is positioned in alignment with the desired dose indicated on the scale and the dose setting limiter is fitted on to the injection device, the position of the protrusion on the third part is locked relatively to the shell, due to the friction between the two parts. When setting up a dose by rotating the dose setting dial, the protrusion on the dose setting dial will be arrested by the protrusion on the third part when the predetermined dose is being reached.

The third part need not be loose and rotational, but could be permanently fastened to the shell. The permanent location of the protrusion on the third part would then be the maximal dose, which could be dialled up when the particular shell is connected to the injection device. Different dose setting limiters each having a different maximal dose setting could be made available for the consumer. This would present a very attractive solution for parents wanting to set a maximal dose on the injection device for a child.

In one embodiment of the dose setting limiter according to the invention the third part can move freely when the first part is disconnected from the housing of the injection device, but is locked to the first part when the first part is connected to said housing. The locking is usually

done by friction between the injection device, but the ring and the shell could also be preformed by a tooth gearing between the shell and the ring, the ring e.g. having pawls being arrested in depressions in the shell, or by other adequate means arresting the ring when the shell is being connected to injection device.

The locking is according to another embodiment of the dose setting limiter according to the invention done by a number of holes in the third part being arrested by a number of raised studs on the inside surface of the first part. With the shell being disconnected from the injection device, the user is provided with a clicking feeling, and a click sound, when the ring is rotated relatively to the shell, due to the engagement between the holes in the ring and the raised studs on the shell.

In a preferred embodiment of the dose setting limiter according to the invention the means located on the second part and the means on the third part are protrusions. Protrusions are easily manufactured and abut one another in a useful manner.

The third part is according to yet another embodiment of the dose setting limiter according to the invention a flat circular ring fitted inside the first part and the protrusion protrudes inwardly pointing towards the centre of the circular ring. By making the third part as a flat ring the thickness of the dose setting limiter can be kept very little. Due to this the total size of the injection device is almost unchanged when the auxiliary dose setting limiter is connected to the injection device.

In a fifth embodiment of the dose setting limiter according to the invention the second part, forming a dose setting dial, is circular and rotational connected to the first part and has the protrusion protruding outwardly. By making the dose setting dial circular it fits onto a large variety of injection devices, while such devices traditionally has a circular dose setting knob.

In yet another embodiment of the dose setting limiter according to the invention the first part, forming a shell, is circular and has a plurality of flanges, which flanges fits retentively around said housing, thereby locking said shell to said housing. The shell can be made to fit very tightly to the injection device, making it almost impossible for people with only limited physical strength to remove the dose setting limiter. In that way parental setting of a predetermined dose is irreversible for a child.

In a further embodiment of the dose setting limiter according to the invention the shell has an area on the circular periphery cut off, making the ring accessible for rotation relative to the shell. This allows the user to get a good grip with the fingers on the ring when setting up a dose.

In yet a different embodiment of the dose setting limiter according to the invention the shell is transparent and the ring has a marker visible through the shell, which marker indicates the location of the protrusion on the ring. Since the marker is visible through the transparent shell the preset dose can easily be read on the scale of the shell.

According to the last embodiment of the dose setting limiter according to the invention the dose setting dial can only be rotated until the protrusion on the dose setting dial is arrested by the protrusion on said ring. With the ring being locked onto the shell it is impossible to rotate the dose setting dial beyond the predetermined dose.

Brief Description of the Drawings:

The invention will be explained more fully below in connection with a preferred embodiment and with reference to the drawing in which:

Figure 1 Shows the auxiliary dose setting limiter according to the invention disconnected from the injection device.

Figure 2 Shows the auxiliary dose setting limiter according to the invention fitted on to a short injection device.

Figure 3 Shows the auxiliary dose setting limiter according to the invention.

Figure 4 Shows an exploded view of the auxiliary dose setting limiter according to the invention.

The figures are schematic and simplified for clarity, and they just show details, which are essential to the understanding of the invention, while other details are left out. Throughout, the same reference numerals are used for identical or corresponding parts.

Detailed Description of Embodiments:

The auxiliary dose setting limiter 5 shown in figures 1 to 4 comprises of three parts 1, 2, 3. A stationary first part 1 having form as a shell, which is fitted over the injection device 4. The shell 1 is made up from a transparent scale-part carrying a scale indicating the doses and having flanges, which flanges fits retentively over the sides of the injection device 4, thereby locking the shell 1 on to the injection device 4. The flanges can be provided with a griping part that abuts the backside of the injection device.

The second part 2 is the dose setting dial, which fits over the dose setting knob of the injection device and is rotated together with this dose setting knob when setting up a dose. The dose setting dial 2 has a recession 6 into which the shell 1 is placed thereby connecting the shell 1 and the dose setting dial 2 together while allowing the dose setting dial 2 to rotate relatively to the shell. The dose setting dial 2 is marked with a pointer 7, which in co-operation with the stationary scale on the shell 1 indicates the set dose. Located on the periphery of the dose setting dial is a protrusion 8 protruding outwardly. This protrusion 8 is placed adjacent the pointer 7 on the dose setting dial 2.

The third part 3 is a flat circular ring, which is placed in a not shown recession on the backside of the shell 1. Depending on the width of the ring 3 it can be captured between the shell 1 and the dose setting dial 2. The ring 3 can rotate freely relatively to both the shell and the dose setting dial 2 when the shell 1 is disconnected from the injection device 4. When the user connects the dose setting limiter 5 to the injection device 4, the ring 3 is locked to the shell 1 making the ring 3 non-rotational relatively to the shell 1. The locking is done by friction between the injection device 4, the ring 3 and the shell 1. To increase the friction the ring 3 is equipped with a number of holes 12, which holes 12 are arrested by one or more not shown raised studs placed on the inside surface of the shell 1. One such hole 12 could be provided for each dial indicated on the transparent scale-part. A not shown tooth gearing between the shell 1 and the ring 3 can also perform the locking. The ring 3 is equipped with a protrusion 10 protruding inwardly and pointing towards the centre of the ring 3. This protrusion 10 has the same width as the finger grip on the dose setting dial 2 and carries a marker 9 indicating the centre of the protrusion 10.

In use the auxiliary dose setting limiter 5 is set while being disconnected from the injection device. The setting of the desired dose is simply done by rotating the ring 3 relatively to the

shell 1 until the marker 9 is placed over the correct dose indication on the scale located on the shell 1. For accommodating an easy rotation of the ring 3, the shell 1 has two areas 11 on the circular periphery cut off for allowing the fingers of the user to grip on the ring 3.

When the correct dose has been pre-set the dose setting limiter 5 is placed onto the injection device 4 by pressing the two flanges over the housing of the injection device 4. This operation locks the ring 3 on to the shell 1. The injection device 4 with the auxiliary dose setting limiter 5 is now ready for use. Next time the user sets up a dose by rotating the dose setting dial 2 the protrusion 8 on the dose setting dial 2 will be arrested by the protrusion 10 on the ring 3 when the pre-set dose has been reached. In this way it may be ensured that a set maximum dose is not exceeded. With the described placements of the two protrusions 8, 10 the set dose will be the dose indicated on the scale, but other placements of the protrusion 8, 10 are possible. If wanted other means instead of protrusions 8, 10 could be used. The means could be a raised stud placed on the dose setting dial 2 and a depression placed on the ring 3 or vice versa, while the two parts 2, 3 could overlap one another.

The ring 3 could be permanently fastened to the shell 1, e.g. by providing the not shown raised studs located on the inside surface of the shell 1 with barbs or other retention means at their outer ends thereby preventing removal of the ring once it has been connected to the shell 1. The two parts 1, 3 could even be moulded as a unitary part. The protrusion 10 would then have a permanent location on the shell indicating the maximal dose, which can be dialled up on the injection device carrying the particular dose setting limiter 5. It would then be necessary to provide the user with different dose setting limiters 5 each having a different maximal dose setting. Parents could then provide the injection device used by their child with a dose setting limiter 5 having a predetermined maximal dose suitable for that individual child. In this way children performing self-injections would not be able to administer a dose large than predetermined by the parents.

Some preferred embodiments have been shown in the foregoing, but it should be stressed that the invention is not limited to these, but may be embodied in other ways within the subject matter defined in the following claims.

All though the present invention has been described in connection with a very short injection device 4 it is obvious that the dose setting limiter 5 as defined in the claims, with some minor adjustments can be used for a large variety of injection devices 4.

Claims:

1. A dose setting limiter (5) for medical injectors (4) of the type having a housing accommodating an ampoule containing medicine sufficient for a number of dosed injections, a rotary dose setting knob, which is rotational relative to said housing and by which doses may be set by rotating said dose setting knob and an injection button which, when activated, administers the set dose, said dose setting limiter comprising:

a stationary first part (1) connected to said housing, and

a second part (2) fitted over said rotary dose setting knob, said second part (2) being able to rotate together with said dose setting knob when setting up a dose and said second part (2) being rotational relatively to said first part (1),

Characterized in that

a third part (3) is placed between said first part (1) and said second part (2), said third part (3) having means (10) co-operating with means (8) on said second part (2) for limiting the dose setting.

2. A dose setting limiter according to claim 1, characterized in that said third part (3) can move freely when said first part (1) is disconnected from said housing, but is locked to said first part (1) when said first part (1) is connected to said housing.

3. A dose setting limiter according to claim 2, characterized in that said third part (3) is locked to said first part (1) by a number of holes (12) in said third part (3) being arrested by a number of raised studs on the inside surface of said first part (1).

4. A dose setting limiter according to anyone of claims 1 to 3, characterized in that said means (8) on said second part (2) and that said means (10) on said third part (3) are protrusions.

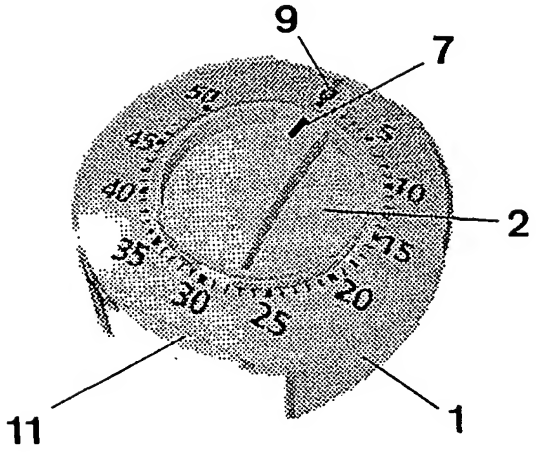

Fig. 1

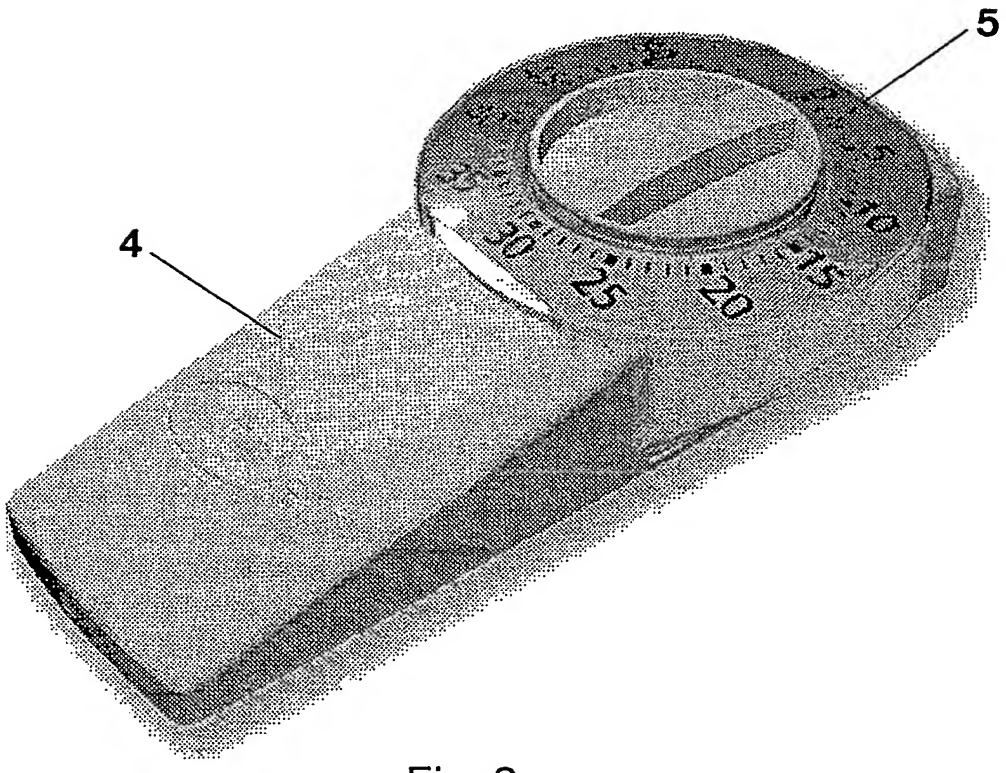

Fig. 2

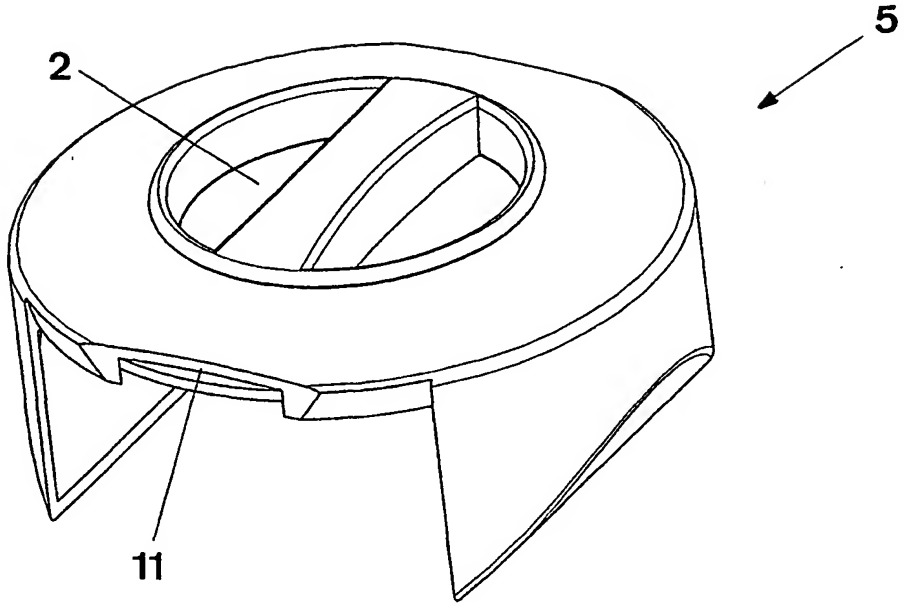

Fig. 3

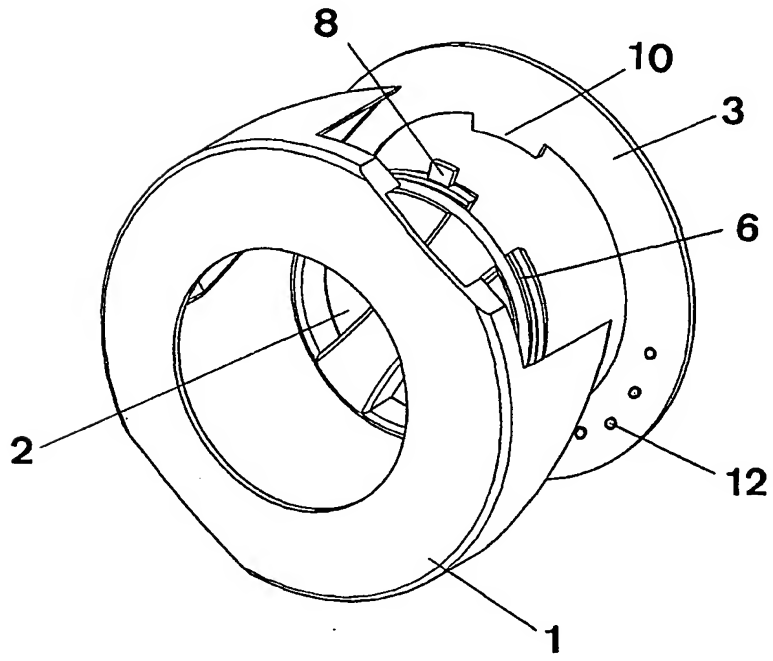

Fig. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 01/00035

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 5/315
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9810813 A1 (NOVO NORDISK A/S), 19 March 1998 (19.03.98) --	1-10
A	WO 9964092 A1 (OWEN MUMFORD LIMITED), 16 December 1999 (16.12.99) --	1-10

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the International Searching Authority European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel(+31-70)340-2040, Tx 31 651 epo nl, Fax(+31-70)340-3016	Authorized officer JACK HEDLUND/EÖ Telephone No.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9810813 A1	19/03/98	AU 726722 B	16/11/00
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